

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Interference No. 104,761

UNIVERSITY OF NEW MEXICO
(5,747,332),
Junior Party,

v.

FORDHAM UNIVERSITY
(09/090,754),
Senior Party.

Entered: 18 August 2003

Before SCHAFER, TORCZON, and SPIEGEL, Administrative Patent Judges.

TORCZON, Administrative Patent Judge.

DECISION ON MOTIONS
(PURSUANT TO 37 CFR 1.640)

INTRODUCTION

This proceeding concerns heat-shock proteins (hsps), particularly methods of isolating hsp complexes and the isolated hsp complexes themselves. Such proteins appear to be induced by the presence of misfolded proteins and appear to stabilize and partially repair such misfolded proteins.

FACT FINDINGS

The following findings are supported by at least a preponderance of the evidence:

- [1] UNM refers to the junior party, the University of New Mexico.

- [2] Fordham refers to the senior party, Fordham University.
- [3] ADP refers to adenosine diphosphate.
- [4] ATP refers to adenosine 5'-triphosphate.
- [5] Hydrolysis of ATP produces ADP plus energy for work in many enzymatic systems.
- [6] There are three counts in the interference.
- [7] The first count, count 1, is "The method of UNM 332 claim 10 or Fordham claim 62."
- [8] UNM 332 claim 10 depends from UNM claim 1 and reads (with claim 1 inserted in brackets):

The method of claim 1 [A method for purifying heat shock protein complexes comprising the steps of:

adding a heat shock protein complex comprising a heat shock protein associated with at least one member of the group consisting of peptides, polypeptides, denatured proteins and antigens associated therewith to ADP matrix column containing an ADP matrix to bind the heat shock protein complexes to the ADP matrix; and

adding a buffer containing ADP to the column to remove the heat shock protein complexes in an elution product.]

wherein the heat shock protein complexes include complexes in which the heat shock protein comprises one of the group consisting of DnaK proteins from prokaryotes; Ssa, Ssb, and Ssc from yeast; hsp70, Grp75 and Grp78(Bip) from eukaryotes.

- [9] Fordham 754 claim 62 is:

A method for purifying heat shock protein 70 complexes, comprising the steps of:

adding a solution containing a heat shock protein 70 complex comprising a heat shock protein 70 associated with at least one member of the group consisting of peptides and proteins, to an ADP matrix column containing an ADP matrix to bind the heat shock protein 70 complexes to the ADP matrix; and

adding a buffer containing ADP to the column to remove the heat shock protein 70 complexes in an elution product.

[10] UNM discloses (1066 at 3:58-60):

Members of the hsp70 family include DnaK proteins from prokaryotes, Ssa, Ssb, and Ssc from yeast, hsp70, Grp75 and Grp78(Bip) from eukaryotes.

[11] The claims corresponding to count 1 are:

UNM 332: 1, 3-5, and 7-12

Fordham: 60, 62-64, 78, 89, 90, and 92

[12] The parties were accorded the benefit of the following constructive reductions to practice for count 1:

For UNM: the involved 5,747,332 patent, issued 5 May 1998 (08/717,239, filed 20 September 1996); and

For Fordham: the 08/527,391 application,¹ filed 13 September 1995 (5,837,251, issued 17 November 1998).

[13] The second count, count 2, is "The method of UNM 332 claim 22 or Fordham claim 65."

[14] UNM 332 claim 22 depends from UNM claim 13 and reads (with claim 13 inserted in brackets):

The method of claim 13 [A method for synthesizing heat shock protein complexes comprising the steps of:

adding a heat shock protein to an ADP matrix column to bind the heat shock protein;

adding a complexing solution comprising a complexing agent selected from the group consisting of peptides, polypeptides, denatured proteins and antigens to the column to form a

¹ The parent of Fordham's involved 754 application.

heat shock protein complex with the heat shock protein bound to the ADP matrix column; and

adding a buffer containing ADP to the column to remove the heat shock protein complex in an elution product]

wherein the heat shock protein complexes include complexes in which the heat shock protein comprises one of the group consisting of DnaK proteins from prokaryotes; Ssa, Ssb, and Ssc from yeast; hsp70, Grp75 and Grp78(Bip) from eukaryotes.

[15] Fordham 754 claim 65 is:

A method of synthesizing heat shock protein 70 complexes, comprising adding a heat shock protein 70 and an antigenic molecule selected from the group consisting of peptides and proteins, to a buffer containing ADP to allow the heat shock protein 70 to bind to the antigenic molecule and ADP to form a heat shock protein 70 complex.

[16] The claims corresponding to count 2 are:

UNM 332: 13, 15-17, and 19-23

Fordham: 65-67, 79, 80, and 93

[17] The parties were accorded the benefit of the following constructive reductions to practice for count 2:

For UNM: the 239 application, filed 20 September 1996; and

For Fordham: the 391 application, filed 13 September 1995.

[18] The third count, count 3, is "The ADP-heat shock protein-peptide complex of UNM 716 claims 13, 19, or 25."

[19] UNM 716 claims 13, 19, and 25 read:

13. A purified ADP-heat shock protein-peptide complex, wherein said heat shock protein is selected from the group consisting of DnaK proteins from prokaryotes.

19. A purified ADP-heat shock protein-peptide complex, wherein said heat shock protein is selected from the group consisting of Ssa, Ssb, and Ssc from yeast.

25. A purified ADP-heat shock protein-peptide complex, wherein said heat shock protein is selected from the group consisting of Grp75 and Grp78(Bip) from eukaryotes.

[20] The claims corresponding to count 3 are:

UNM 716: 13-30
Fordham: 68-75 and 82-88

[21] The parties were accorded the benefit of the following constructive reductions to practice for count 3:

For UNM: the 239 application,² filed 20 September 1996; and

For Fordham: the 391 application, filed 13 September 1995.

[22] UNM has filed five preliminary motions:

- 1 To designate UNM 332 claims 8, 9, and 11 as not corresponding to count 1 and to designate UNM 332 claims 20, 21, and 23 as not corresponding to count 2;
- 2 For judgment that the Fordham involved claims are not patentable under 35 U.S.C. 103;
- 3 To strip Fordham of the benefit of its 391 parent application as a constructive reduction to practice;
- 4 To designate Fordham claims 94 and 95 as corresponding to count 3; and
- 5 Contingent on the granting of Fordham's preliminary motion 1, to be accorded the benefit of UNM's 239 parent application.

[23] Fordham has filed four preliminary motions:

² The application that issued as the involved UNM 332 patent and the parent application for the application that issued as the involved UNM 716 patent.

- 1 To change the count by substituting proposed count 4 for present count 2;
- 2 Contingent on the granting of its preliminary motion 1, to be accorded the benefit of its 391 parent application as a constructive reduction to practice for proposed count 4;
- 3 To add claim 96 and have it designated as corresponding to count 2;
- 4 To designate UNM 332 claims 2 and 6 to count 1, UNM claims 14 and 18 to count 2, and UNM 716 claims 7-12 to count 3.

Substitution of count 4 for count 2

- [24] Fordham proposes the following count 4 (strikethrough indicates deletion; underlining, addition):

[UNM 332 claim10] The method of claim 1 wherein the heat shock protein complexes include complexes in which the heat shock protein comprises one of the group consisting of DnaK proteins from prokaryotes; Ssa, Ssb, and Ssc from yeast; hsp70, Grp75 and Grp(78) [sic, Grp78(Bip)] from eukaryotes.

OR

[Fordham claim 65, modified] A method of synthesizing heat shock protein 70 complexes, comprising ~~adding~~ contacting a heat shock protein 70 ~~and with~~ an antigenic molecule selected from the group consisting of peptides and proteins, ~~to~~ and with a buffer containing ADP to allow the heat shock protein 70 to bind to the antigenic molecule and to allow the heat shock protein 70 to bind to the ADP to form a heat shock protein 70 complex.

- [25] The stated purpose of the substitution is to eliminate the implicit ordering of the steps in Fordham claim 65 in order to encompass Fordham's best proofs (Paper 63³ at 5).
- [26] According to Fordham (Paper 63 at 5), its:

best proofs for synthesis of a hsp70-ADP-antigenic molecule ternary complex involve incubation of hsp70 and the antigenic molecule for a

³ Fordham Preliminary Motion 1.

period of time in a first solution, followed by addition of ADP to that first solution.

[27] The proposed count 4 garbles existing count 2 because it substitutes UNM 332 claim 10 in the place of UNM 332 claim 22.

[28] Based on the rest of Fordham's motion, it appears that this substitution of count 2 was not intended.

[29] We understand proposed count 4 to be:

The method of UNM 332 claim 22

OR

A method of synthesizing heat shock protein 70 complexes, comprising contacting a heat shock protein 70 with an antigenic molecule selected from the group consisting of peptides and proteins, and with a buffer containing ADP to allow the heat shock protein 70 to bind to the antigenic molecule and to allow the heat shock protein 70 to bind to the ADP to form a heat shock protein 70 complex.

[30] Fordham states that while the elimination of any implicit order broadens the count, the order of the steps is not relevant to patentability.

[31] We understand Fordham to be admitting that a person having ordinary skill in the art would see no patentable distinction between any of the operative permutations for mixing the reagents.

[32] We note that Fordham's proposed claim 96 is the same as the modified version of claim 65 that now constitutes one of the alternatives under count 4.

Fordham's entitlement to its 391 application as a constructive reduction to practice

Count 1

[33] Fordham 754 claim 62, which forms an alternative of count 1, is

A method for purifying heat shock protein 70 complexes, comprising the steps of:

adding a solution containing a heat shock protein 70 complex comprising a heat shock protein 70 associated with at least one member of the group consisting of peptides and proteins, and an ADP matrix column containing an ADP matrix to bind the heat shock protein 70 to the ADP matrix; and

adding a buffer containing ADP to the column to remove the heat shock protein 70 complexes in an elution product.

- [34] According to Fordham (Fordham PM Opp. 3 at 9), the 391 application provides the following support for its claim 62 (1036⁴ at 25:1-17):

The present invention further describes a new and rapid method for purification of hsp70-peptide complexes. This improved method comprises contacting cellular proteins with ADP or a nonhydrolyzable analog of ATP affixed to a solid substrate, such that hsp70 in the lysate can bind to the ADP or nonhydrolyzable ATP analog, and eluting the bound hsp70. A preferred method uses column chromatography with ADP affixed to a solid substratum (e.g., ADP-agarose). The resulting hsp70 preparations are higher in purity and devoid of contaminating peptides. The hsp70 yields are also increased significantly by about more than 10 fold. Alternatively, chromatography with nonhydrolyzable analogs of ATP, instead of ADP, can be used for purification of the hsp70-peptide complexes. By way of example but not limitation, purification of hsp70-peptide complexes by ADP-agarose chromatography was carried out as described in Example Section 9.

and (1036 at 60:5-25):

**9. EXAMPLES: METHOD FOR RAPID PURIFICATION
OF PEPTIDE-ASSOCIATED HSP70**

Hsp70-peptide complexes can be readily obtained from cancer cells or cells infected by an infectious agent or other cells by an infectious agent or other cells by a rapid, one-step ADP-agarose chromatography, described below.

⁴ Specification for Application No. 08/527,391. Senior party exhibits are numbered 1xxx.

9.1 Method and Results

Meth A sarcoma cells (500 million cells) were homogenized in hypotonic buffer and the lysate was centrifuged at 100,000 g for 90 minutes at 4°C. The supernatant was divided into two and was applied to an ADP-agarose or ATP-agarose column. The columns were washed in buffer and were eluted with 3 mM ADP or 3 mM ATP, respectively. The eluted fractions were analyzed by SDS-PAGE: in both cases, apparently homogeneous preparations of hsp70 were obtained. However, when each of the preparations was tested for presence of peptides, the ADP-bound/eluted hsp70 preparation was found to be associated with peptides, while the ATP-bound/eluted hsp70 preparation was not. (FIGS. 5B and 5A, respectively).

- [35] The supernatant in Section 9 supports the "solution containing a heat shock protein complex comprising heat shock protein 70 associated with...peptides".
- [36] The supernatant is applied to an "ADP matrix column" to which the hsp70 binds.
- [37] An elution product is obtained using an ADP-containing buffer.
- [38] The 391 application contains at least one embodiment within the scope of Fordham claim 62, and hence within the scope of count 1.

Count 2/4

- [39] Count 4, which contains a modified version of Fordham 754 claim 65 as follows:

A method of synthesizing heat shock protein 70 complexes, comprising contacting a heat shock protein 70 with an antigenic molecule selected from the group consisting of peptides and proteins, and with a buffer containing ADP to allow the heat shock protein 70 to bind to the antigenic molecule and to allow the heat shock protein to bind to the ADP to form a heat shock protein 70 complex.

- [40] According to Fordham (Fordham PM Opp. 3 at 9), the 391 application provides the following support for its claim 65 (1036 at 36:25-32):

In an alternative embodiment of the invention, preferred for producing complexes of hsp70 to exogenous antigenic molecules such as proteins, 5-10 micrograms of purified hsp is incubated with equimolar

quantities of the antigenic molecule in 20mM sodium phosphate buffer pH 7.5, 0.5M NaCl, 3mM MgCl₂ and 1mM ADP in a volume of 100 microliter [sic, microliters] at 37°C for 1 hr. This incubation mixture is further diluted to 1ml in phosphate-buffered saline.

- [41] This alternative embodiment incubates purified hsp with ADP and antigenic molecules to produce "complexes of hsp70 to exogenous antigenic molecules". Although the purified hsp is not specifically identified, one skilled in the art would infer from the resulting complex that the purified hsp must be hsp70.
- [42] The 391 application contains at least one embodiment within the scope of the modified version of Fordham claim 65, and hence within the scope of count 2.

Count 3

- [43] Count 3 is "The ADP-heat shock protein-peptide complex of UNM 716 claims 13, 19, or 25", which in expanded form is:

[Claim 13] A purified ADP-heat shock protein-peptide complex, wherein said heat shock protein is selected from the group consisting of DnaK proteins from prokaryotes [or]

[Claim 19] A purified ADP-heat shock protein-peptide complex, wherein said heat shock protein is selected from the group consisting of Ssa, Ssb, and Ssc from yeast [or]

[Claim 25] A purified ADP-heat shock protein-peptide complex, wherein said heat shock protein is selected from the group consisting of Grp75 and Grp78(Bip) from eukaryotes.

- [44] According to Fordham (Fordham PM Opp. 3 at 10), its description of methods for purifying and for synthesizing hsp70-peptide complexes, both of which include ADP in the elution or incubation step, respectively, necessarily produce purified ADP-hsp-peptide complexes.

- [45] As previously noted, the hsp70 family includes DnaK proteins from prokaryotes; Ssa, Ssb, and Ssc from yeast; and hsp70, Grp75, and Grp78(Bip) from eukaryotes [2066 at 3:58-60].
- [46] Note that while UNM discloses hsp70 in eukaryotes as an hsp70 family member, it is not included as a Markush alternative in any of the claims making up count 3.
- [47] According to Fordham [1036 at 15:32-16:24]:

Heat shock proteins, which are also referred to interchangeably herein as stress proteins, useful in the practice of the instant invention can be selected from among any cellular protein that satisfies any one of the following criteria. It is a protein whose intracellular concentration increases when a cell is exposed to a stressful stimuli, it is capable of binding other proteins or peptides, it is capable of releasing the bound proteins or peptides in the presence of adenosine triphosphate (ATP) or low pH, or it is a protein showing at least 35% homology with any cellular protein having any of the above properties.

The first stress proteins to be identified were the heat shock proteins (hsps). As their name implies, hsps are synthesized by a cell in response to heat shock. To date, three major families of hsp have been identified based on molecular weight. The families have been called hsp60, hsp70 and hsp90 where the numbers reflect the approximate molecular weight of the stress proteins in kilodaltons. Many members of these families were found subsequently to be induced in response to other stressful stimuli, including, but not limited to, nutrient deprivation, metabolic disruption, oxygen radicals, and infection with intracellular pathogens. [citations omitted.] It is contemplated that hsps/stress proteins belonging to all of these three families can be used in the practice of the instant invention.

- [48] Fordham continues [1036 at 16:36-17:18]:

Heat shock proteins are among the most highly conserved proteins in existence. For example, DnaK, the hsp70 from *E. coli* has about 50% amino acid sequence identity with hsp70 proteins from eukaryotes [sic, citation omitted]. The hsp60 and hsp90 families also show similarly high levels of intra families conservation [citations omitted]. In addition, it has been discovered that the hsp60, hsp70 and hsp90 families are composed of proteins that are related to the stress proteins in sequence, for

example, having greater than 35% amino acid identity, but whose expression levels are not altered by stress. Therefore it is contemplated that the definition of stress protein, as used herein, embraces other proteins, muteins, analogs, and variants thereof having at least 35% to 55%, preferably 55% to 70%, and most preferably 75% to 85% amino acid identity with members of the three families whose expression levels in a cell are enhanced in response to a stressful stimulus. The purification of stress proteins belonging to these three families is described below.

- [49] In context, Fordham has provided adequate blaze marks to those skilled in the art to determine that methods of purifying hsp70 complexes are intended to extend at least to purification of DnaK complexes as well.
- [50] The 391 application provides support for a method to produce ADP-DnaK-peptide complexes, which are within the scope of count 3.
- [51] Dr. William Welch, a UNM expert witness, in discussing his own research points [2028 at 5] to a 1983 paper [2034]⁵ showing DnaK binding to ATP as his inspiration to use immobilized ATP to purify other hsp70 family members.

Correspondence of UNM claims 8, 9, 11, 20, 21, and 23

- [52] UNM 332 claims 8, 9, and 11 correspond to count 1, which is based in part on UNM 332 claim 10.
- [53] UNM 332 claims 20, 21, and 23 correspond to count 2, which is based in part on UNM 332 claim 22 (as is substituted count 4).
- [54] Claims 8, 9, and 11 depend, like claim 10, from 332 claim 1.
- [55] Claims 20, 21, and 23 depend, like claim 22, from claim 13.
- [56] Where claims 10 and 22 add the further limitation:

⁵ M. Zylitz et al., "The DnaK protein of *E. Coli* possesses an ATPase and autophosphorylation activity and is essential in an *in vitro* DNA replication system", 80 Proc. Nat'l Acad. Sci. USA 6431 (1983).

wherein the heat shock protein complexes include complexes in which the heat shock protein comprises one of the group consisting of DnaK proteins from prokaryotes; Ssa, Ssb, and Ssc from yeast; hsp70, Grp75 and Grp78(Bip) from eukaryotes.

Claims 8 and 20 instead add the further limitation:

wherein the heat shock protein complexes include complexes in which the heat shock protein comprises one of the group consisting of hsp60, hsp65, rubisco binding protein and TCP-1 from eukaryotes; GroEL/GroES, Mif4, TCPalpha and TCPbeta from yeast.

Claims 9 and 21 instead add the further limitation:

wherein the heat shock protein complexes include complexes in which the heat shock protein comprises one of the group consisting of hsp104, hsp105, and hsp110.

And claims 11 and 23 instead add the further limitation:

wherein the heat shock protein complexes include complexes in which the heat shock protein comprises one of the group consisting of hsp90, g96, and grp94.

- [57] All six claims to be designated as not corresponding are in Markush format, in that the heat-shock protein in the complex is to be selected from a list of heat-shock proteins.
- [58] The hsp70 family of heat-shock proteins is just one of a large number of heat-shock protein families (Paper 58,⁶ admitted fact 6).
- [59] UNM contends that each of the alternate families of heat shock proteins recited in the claims to be undesignated varies significantly from the hsp70 family in claims 10 and 22. It points to significant differences in amino acid sequences (primary structure), multimer formation (quaternary structure), and crystal structure (e.g., Paper 58, admitted facts 7-9, 12 & 13).

⁶ UNM Preliminary Motion 1.

- [60] Fordham notes that counts 1 and 2/4 are drawn to methods of purifying and synthesizing hsp complexes, which rely on the biological functions of heat-shock proteins rather than any particular feature of hsp70 structure. Specifically, Fordham notes that it is sufficient for the methods, which use affinity chromatography, that heat-shock proteins uniformly be known to bind with proteins and ADP. This is so because the complexes are formed between the particular heat-shock protein and another protein, while the affinity exploited in the chromatography is heat-shock protein affinity for ADP [Paper 74.500⁷ at 2].
- [61] Hsp70 is also called "stress-70" to reflect the fact that heat-shock proteins can exist constitutively or can be induced by a variety of stresses other than heat [1028⁸ at 35].
- [62] Hsp70 binds with proteins, ATP, and ADP in cells [1028 at 38].
- [63] While the effects of ATP and ADP on heat-shock proteins can vary, one key distinction is that ATP can cause hsp70-protein complexes in cell extracts to dissolve [1028 at 38].
- [64] Since affinity chromatography for synthesizing or purifying hsp-protein complexes is performed with cell extracts, avoiding the use of ATP, which might make the complexes dissolve, would have been desirable.

Claims 8 and 20

- [65] Claims 8 and 20 list hsp60 and GroEL/GroES as Markush options.

⁷ Fordham Opposition to UNM Preliminary Motion 1. The odd paper number is an artifact of the growing pains of the electronic filing pilot program.

⁸ M.-J. Gething & J. Sambrook, Review article "Protein folding in the cell", 355 Nature 33 (1992) ("Gething").

- [66] GroEL is a hsp60 family member in *E. coli*. GroES is a smaller heat-shock protein that works with GroEL in an ATP-dependent manner [1028 at 42].
- [67] As of 1992, one skilled in the art would have expected hsp60 family complexes to behave similarly to hsp70 family complexes with respect to protein binding and ADP affinity [1028 at 42]:

Remarkably, the general features of the interactions of chaperonin-60 molecules with their target polypeptides are very similar to those of stress-70 proteins, despite great differences in their sequences and oligomeric structures (for recent reviews and references see [omitted]). Thus, both types of chaperones are highly abundant proteins whose rate of synthesis can be further induced by environmental stresses such as heat shock. Members of both families have been implicated in the assembly of nascent protein subunits into macromolecular structures, as well as in a number of other fundamental cellular processes. Chaperonin-60 molecules, like stress-70 proteins, bind ATP with high affinity and have weak ATPase activity and both types of proteins in some circumstances function together with other heat-shock proteins or cellular factors. Most importantly, both seem to act on their targets by stabilizing the conformation of folding intermediates, thereby preventing the formation of aberrant structures and directing the polypeptides down biologically productive assembly pathways.

- [68] The weak ATPase activity involves the hydrolysis of ATP to ADP, which appears to be involved in the ATP-driven release of the peptide from the hsp60-peptide complex, which also occurs in hsp70 complexes [1028 at 42]:

This second possibility is compatible with the suggestion that, in the presence of GroES, the folding of DHFR and rhodanese on the surface of GroEL occurs by progressive ATP hydrolysis-dependent release of different portions of the bound peptide.

- [69] DHFR and rhodanese are cellular proteins.

- [70] This binding and releasing can occur without ATP, but appears to be more efficient when ATP is involved [1024⁹ at 10041].
- [71] At the time of the Gething review article (1992), questions remained about the precise role that ATP hydrolysis played in heat-shock protein polypeptide binding and folding [1028 at 43].
- [72] Other research indicates that ADP promotes the formation and stability of hsp-protein complexes, at least in the hsp70 family [2030¹⁰ at 13110]. The authors suggest that it is the decrease in ATP relative to ADP that triggers hsp complexing activity in the aftermath of stress with the eventual increase in ATP being the signal to decrease hsp complexing activity because the situation is returning to normal [2030 at 13114].
- [73] Despite their similar functions, particularly with respect to binding proteins and hydrolyzing ATP, hsp60 and hsp70 have markedly different quaternary structures [1028 at 43].

Claims 9 and 21

- [74] Claims 9 and 21 include hsp110 as a Markush option for the heat-shock protein.
- [75] In redeclaring the interference (Paper 40), the administrative patent judge assigned to the interference declined to designate hsp110 claims as corresponding to count 3, which is directed to specific ADP-hsp70 family-protein complexes themselves rather

⁹ U. Jakob et al., "Assessment of the ATP Binding Property of Hsp90", 271 J. Biol. Chem. 10035 (Apr. 1996).

¹⁰ D.R. Palleros, L. Shi, K.L. Reid & A.L. Fink, "hsp70-Protein Complexes", 264 J. Biol. Chem. 13107 (1994) ("Palleros").

than to a method of synthesizing or purifying ADP-hsp-protein complexes on the basis of the following statement in Fordham's Exhibit 1010¹¹ [at 15725]:

The analysis presented here demonstrates that hsp110 is a large and highly unusual member of the hsp70 family, a molecule that shares specific common structural features with the sea urchin egg receptor for sperm.

- [76] Although the sequence identity between hsp110 and hsp70 family members is relatively low (30-33%), the Lee-Yoon article nevertheless concludes that its is similar enough in sequence at certain functional sites to warrant classification as a member of the hsp70 family [1010 at 15725 & 15728].
- [77] Note that Fordham, in listing functional criteria for meeting its definition of a heat-shock protein, expressly includes as an alternative cellular proteins with at least 35% sequence homology and at least one hsp property [1036 at 1036 at 15:36-16:5]
- [78] Most of the similar sequences occur in the ATP-binding domains of hsp70 and hsp110 [1010 at 15725 & 15728].
- [79] Surprisingly, the mammalian hsp110 had greater sequence homology with SSE heat shock proteins from yeast than with typical mammalian hsp70 family members [1010 at 15729].
- [80] While the five functional domains (two phosphate-binding domains, an adenosine-binding domain, and two connecting structures defining the active site) of the putative hsp110 ATP-binding domain were highly conserved in comparison to the analogous hsp70 domains, and thus suggesting that ATP-binding is an important function of

¹¹ D. Lee-Yoon et al., "Identification of a Major Subfamily of Large hsp70-like Proteins through the Cloning of the Mammalian 110-kDa Heat Shock Protein", 270 J. Biol. Chem. 15725 (June 1995) ("Lee-Yoon").

hsp110, the Lee-Yoon article cautions that a similar site in the sea urchin egg receptor is believed to have lost its function. Consequently, the article recommends that further experimentation be done to determine the ATP-binding properties of hsp110 [1010 at 15732].

[81] In hsp70, the ATP-binding site hydrolyzes ATP to ADP.

[82] The hsp110 carboxyl terminal is not as well conserved (only ~40% similarity) in comparison with the carboxyl terminal of hsp70 family members, which in hsp70 is responsible for peptide binding [1010 at 15725 & 15732].

[83] With regard to protein binding, Lee-Yoon article states [1010 at 15732]:

Since hsp110 has a putative ATP-binding domain, which in hsp70 appears to function in the regulation of peptide binding, it is likely that the proteins of the hsp110/SSE subfamily are also peptide-binding proteins with functions paralleling the hsp70 proteins. However, differences in the structure of the carboxyl-terminal regions of hsp110 imply that its protein binding specificity or capacity may be significantly altered.

[84] Subsequent research, published after UNM's effective filing date, confirmed the presence of a functional ATP-binding domain and peptide binding site in hsp110, although the ATP-binding domain is normally masked and is not necessary for protein binding [1015¹² at 15715-16].

[85] Earlier research had failed to find an affinity between hsp110 and ATP [2075 at 340].

[86] While a May 1999 study showed no evidence of hsp110-ATP binding *in vitro* [1015 at 15717], a June 1999 study by a related research group found evidence that hsp110

¹² H.J. Oh et al., "Chaperoning Activity of hsp110", 274 J. Biol. Chem. 15712 (1999) ("Oh").

does bind ATP insofar as ATP reduces with hsp110's ability to bind ribonucleic acid motifs [1016¹³ at 17322].

Claims 11 and 23

- [87] Claims 11 and 23 include g96 as a Markush option for the heat-shock protein.
- [88] UNM appears to use the "g96" in claims 11 and 23 as an alternative name for gp96 [compare 2066¹⁴ at 1:39-50 with 3:64-65].
- [89] Gp96 complexes with proteins, apparently to present them to the immune system, and also binds to ATP, which it hydrolyzes to ADP [1017 at 3143-44 & 3148-49].¹⁵
- [90] Gp96 and hsp70 both bind tightly to ATP and ADP, unlike reference phosphoproteins [1017 at 3144].
- [91] Gp96 appears to hydrolyze ATP to ADP [1017 at 3144].
- [92] ATP does not appear to dissolve gp96-protein complexes [1020¹⁶ at 5402].
- [93] An article published a few months before UNM's earliest effective filing date cast doubt on earlier research suggesting that hsp90 interacts with ATP [1024].
- [94] Earlier work observed that hsp90 has an ATP-binding site and appeared to have an enzymatic function similar to hsp70 [1023¹⁷ at 4943 & 4948].

¹³ T. Henics et al., "Mammalian Hsp70 and Hsp110 Proteins Bind to RNA Motifs Involved in mRNA Stability", 274 J. Biol. Chem. 17318 (1999).

¹⁴ The involved UNM 332 patent.

¹⁵ Z. Li & P. Srivastava, "Tumor rejection antigen gp96/grp94 is an ATPase: implications for protein folding and antigen presentation", 12 EMBO J. 3143 (1993).

¹⁶ H. Udono & P.K. Srivastava, "Comparison of Tumor-Specific Immunogenicities of Stress-Induced Proteins gp96, hsp90, and hsp70", 152 J. Immunol. 5398 (1994).

¹⁷ P. Csermely and C.R. Kahn, "The 90-kDa Heat Shock Protein (hsp90) Possesses an ATP Binding Site and Autophosphorylating Activity", 266 J. Biol. Chem. 4943 (1991).

Structural differences

- [95] UNM argues, and Fordham does not appear to contest, that the various hsp family and subfamily members can have widely diverging primary (sequence) structures, that can result in widely different secondary (domain), tertiary (monomer), and quaternary (multimer) structures.
- [96] UNM observes that there is no question of anticipation of one family by another. We agree.
- [97] The example of hsp110, however, shows that in spite of very great sequence divergence overall, there can be adequate sequence similarity in particular domains to provide similar or identical functionality.
- [98] The example of hsp110 also shows that sequence identity might be meaningless for some domains. Both hsp70 and hsp110 bind to proteins, but their protein binding domains are very different, presumably because they are binding to very different proteins.
- [99] The testimony of UNM witness Dr. Welch [2028 & 2075] regarding the structural differences and non-interchangeability of heat-shock proteins is not especially helpful because the differences he focuses on are not differences that matter with regard to the issue of whether at least one hsp in each claim shares hsp70's affinity for ADP while complexed with a protein.
- [100] While UNM's patents list heat-shock proteins other than hsp70, the only two examples provided involve isolation of hsp70 complexes [1007 & 1008]. No additional explanation is provided on why the examples would work for non-hsp70 heat-shock

proteins nor is there guidance on how the examples should be modified to make them work for non-hsp70 heat-shock proteins.

Designating additional UNM claims as corresponding

[101] Fordham seeks to have the following additional UNM claims designated as corresponding to the indicated counts (Paper 65¹⁸ at 2):

For count 1, 332 claims 2 and 6;

For count 2,¹⁹ 332 claims 14 and 18; and

For count 3, 716 claims 7-12.

UNM 332 claims 2, 6, 14 and 18

[102] UNM 332 claims 2 and 6 depend from claim 1 as does UNM 332 claim 10, which provides one of the alternatives of count 1.

[103] UNM 332 claims 14 and 18 depend from claim 13 as does UNM 332 claim 22, which provides one of the alternatives of count 4.

[104] Claims 1 and 13 are not limited to any specific heat-shock protein or hsp family and, consequently, claims 2, 6, 14, and 18 are not so limited.

[105] UNM 332 claims 2, 6, 14, and 18 are, however, further limited by the requirement of a GTP (or other non-adenosine nucleotide) elution step to wash contaminants away.

[106] GTP is guanosine 5'-triphosphate.

[107] Claim 2 further limits claim 1 as follows:

¹⁸ Fordham preliminary motion 4.

¹⁹ Now count 4, which retains UNM 332 claim 13 as an alternative.

The method of claim 1 further comprising the step of adding a purifying buffer solution comprising at least one member of the group consisting of GTP and a non-adenosine containing nucleotides [sic] to the ADP matrix column to elute proteins that are loosely bound with the ADP matrix column.

[108] Claim 6 further limits claim 1 as follows:

The method of claim 1 further comprising the step of adding a buffer solution containing GTP to the column to elute proteins other than heat shock proteins that are loosely bound to the matrix.

[109] Claim 14 further limits claim 13 as follows:

The method of claim 13 further comprising the step of adding a purifying buffer solution comprising at least one of the group consisting of GTP and a non-adenosine containing nucleotide to the column to elute proteins that are loosely bound with the ADP matrix column.

[110] Claim 18 further limits claim 13 as follows:

The method of claim 13 further comprising the step of adding a buffer solution containing GTP to the column to elute proteins other than heat shock proteins that are loosely bound to the matrix.

[111] Fordham relies on a 1985 Welch article [1014²⁰ at 1230] to show (Paper 65 at 3, Fact 1):

the use of a GTP-containing buffer to elute non-hsp70 proteins from an ATP-agarose column prior to elution of hsp70 proteins with a buffer containing ATP[.]

[112] UNM admits this fact, but questions its relevance because the contested invention involves an ADP matrix, which Welch 1985 does not teach, rather than the ATP matrix that Welch 1985 discloses (Paper 74.300²¹ at 2).

²⁰ W.J. Welch & J.R. Feramisco, "Rapid Purification of Mammalian 70,000-Dalton Stress Proteins: Affinity of the Proteins for Nucleotides", 5 Mol. & Cell. Biol. 1229 (1985), also UNM exhibit 2033. Dr. Welch is a witness for UNM.

²¹ UNM opposition 4.

[113] Fordham admits that Welch 1985 does not teach GTP elution with an ADP matrix.

[114] Welch 1985 provides the following disclosure [1014 at 1230]:

For the purification of the 72- and 73-kDa stress proteins, 40 liters of suspension HeLa cells, growing in F-13 Spinner medium supplemented with 5% calf serum, were incubated at 42.5°C for 5 h. After the heat-shock treatment, the cells were collected by centrifugation, washed with phosphate-buffered saline, and resuspended in hypotonic buffer (10 mM Tris-acetate [pH 7.5], 10 mM NaCl, 0.1 mM EDTA). After maximum swelling, the cells were lysed by Dounce homogenization, and the lysate was centrifuged at 12,000 β g for 15 min. The 12,000 β g supernatant was applied directly to a DE52-cellulose column, the column was washed with buffer B, and the proteins were eluted with a 20 to 350 mM linear gradient of NaCl in buffer B. After analysis of eluted protein by SDS-PAGE, the peak fractions containing the 72- and 73-kDa proteins were pooled and applied directly to an ATP-agarose column (1.0 by 20 cm [sic]), and the column was washed with buffer D containing 0.5M NaCl and then with buffer D alone. The column was first developed with buffer D supplemented with 1 mM GTP, resulting in the specific elution of two poly peptides of ~17 and 20 kDa (see Fig. 2). Subsequently, the column was developed with buffer D containing 3 mM ATP, resulting in the specific elution of the 72- and 73-kDa stress proteins.

[115] Affinity chromatography, which is the isolation method used in the claims, relies on the relatively stronger affinity of the target molecule for the chromatography substrate than for other substrates in its environment.

[116] In the Welch 1985 disclosure, at least two contaminant proteins (17 kDa and 20 kDa) had a greater affinity for GTP than for ATP, while the hsp70 family members isolated had a greater affinity for ATP than for GTP.

[117] Fordham has not given us a basis for finding that either contaminants would have a greater affinity for GTP than ADP or, perhaps more importantly, that targeted heat-shock proteins would have a greater affinity for ADP than GTP.

UNM 716 claims 7-12

- [118] Count 3 is defined in terms of UNM 716 claims 13, 19, and 25, which in turn specify hsp70 family members as follows:

A purified ADP-heat shock protein-peptide complex, wherein said heat shock protein is selected from the group consisting of DnaK proteins from prokaryotes [claim 13]; from the group consisting of Ssa, Ssb, and Ssc from yeast [claim 19]; or from the group consisting of Grp75 and Grp78(Bip) from eukaryotes [claim 25].

- [119] UNM 716 claim 7 is the analogous claim for hsp110 subfamily members:

7. A purified ADP-heat shock protein-peptide complex, wherein said heat shock protein is selected from the group consisting of hsp104, hsp105 and hsp110.

- [120] Claims 8-12 are analogous to UNM 716 claims 14-18, 20-24, and 26-30, which correspond to count 3.

- [121] Claims 8-12 read as follows:

8. The purified ADP-heat shock protein-peptide complex of claim 7, wherein a heat shock protein-peptide portion of said ADP-heat shock protein-peptide complex comprises a non-naturally occurring heat shock protein-peptide combination.

9. The ADP-heat shock protein-peptide complex of claim 8, wherein said heat shock protein-peptide portion of said complex comprises a heat shock protein from one cell and a peptide from a second cell of the same individual.

10. The ADP-heat shock protein-peptide complex of claim 8, wherein said heat shock protein-peptide portion of said complex comprises a heat shock protein from one individual and a peptide from a second individual.

11. The ADP-heat shock protein-peptide complex of claim 8, wherein said heat shock protein-peptide portion of said complex comprises a heat shock protein from one organism and a peptide from a second organism.

12. The ADP-heat shock protein-peptide complex of claim 8, wherein said heat shock protein-peptide portion of said complex comprises a heat shock protein from one species and a peptide from a second species.

[122] Fordham's motion with respect to claims 7-12 is based on the contention that the hsp110 subfamily is part of the hsp70 family. In particular, Fordham relies on the following passages from the Lee-Yoon article [1010 at 15725]:

Therefore, hsp110 belongs to a new category of large and structurally unique stress proteins that are the most distantly related known members of the hsp70 family.

and from the Oh article [1015 at 15712]:

Surprisingly, the cloning of hsp110 family members has indicated that this family does not represent a genetically unique stress protein group as previously seen with other heat shock protein families such as hsp90 or 28, but that they are clearly related to the hsp70 family (14).

[123] The "(14)" in the Oh quote is a citation to the Lee-Yoon article [1015 at 15718].

[124] Fordham also points (Paper 65 at 8) to structural similarities between hsp110 and DnaK [1015 at 15714].

[125] The Oh article was published in 1999, well after UNM's filing dates.

[126] Even taking the post-filing disclosure of Oh into account, DnaK and hsp110 cannot be said to be inherently the same, so we do not understand Fordham to be basing its argument on anticipation or inherency.

[127] The Yoon-Lee article characterizes hsp110 as [1010 at 15725-26]:

a large and highly unusual member of the hsp70 family, a molecule that shares specific common structural features with the sea urchin egg receptor for sperm. [H]sp110, sea urchin egg receptor, and four other recently identified proteins are shown to represent a statistically distinct subfamily of unusual hsp70-related sequences that is conserved from yeast to man. The cloning of hsp110 and the identification of this family

raise a number of new questions about the structure, function, and evolution of these proteins, which are the most highly diverged known members of the hsp70 family.

- [128] As of UNM's filing dates, a person having ordinary skill in the art would have considered hsp110 subfamily members to be very distinct from the canonical hsp70 family members, such as DnaK.

Patentability of Fordham claims 60, 62-75, 78-80, 82-90, and 92-95

- [129] UNM seeks (Paper 59²²) to have Fordham claims 60, 62-75, 78-80, 82-90, and 92-95 held unpatentable in view of five references:

[2030] the Palleros article (1994);

[2033] the 1985 Welch article;

[2041] M.Y. Sherman & A.L. Goldberg, "Formation In Vitro of Complexes between an Abnormal Fusion Protein and the Heat Shock Proteins from *Escherichia coli* and Yeast Mitochondria", 173 J. Bacteriology 7249 (1991) ("Sherman");

[2042] S. Sadis & L.E. Hightower, "Unfolded Proteins Stimulate Molecular Chaperone Hsc70 ATPase by Accelerating ADP/ATP Exchange", 31 Biochemistry 9406 (1992) ("Sadis"); and

[2045] C. Georgopoulos & W.J. Welch, "Role of the Major Heat Shock Proteins As Molecular Chaperones", 9 Ann. Rev. Cell Biol. 601 (1993) ("Georgopoulos").

- [130] Fordham's earliest filing date is 13 September 1995.

- [131] UNM only provides reasons why its claims would not also be obvious for UNM 332 claims 8, 9, 11, 20, 21, and 23.

²² UNM preliminary motion 2.

- [132] Welch 1985 teaches the use of affinity chromatography using an ATP substrate to isolate hsp70 family heat-shock proteins [1014 at 1230]:

For the purification of the 72- and 73-kDa stress proteins, 40 liters of suspension HeLa cells, growing in F-13 Spinner medium supplemented with 5% calf serum, were incubated at 42.5°C for 5 h. After the heat-shock treatment, the cells were collected by centrifugation, washed with phosphate-buffered saline, and resuspended in hypotonic buffer (10 mM Tris-acetate [pH 7.5], 10 mM NaCl, 0.1 mM EDTA). After maximum swelling, the cells were lysed by Dounce homogenization, and the lysate was centrifuged at 12,000 β g for 15 min. The 12,000 β g supernatant was applied directly to a DE52-cellulose column, the column was washed with buffer B, and the proteins were eluted with a 20 to 350 mM linear gradient of NaCl in buffer B. After analysis of eluted protein by SDS-PAGE, the peak fractions containing the 72- and 73-kDa proteins were pooled and applied directly to an ATP-agarose column (1.0 by 20 cm [sic]), and the column was washed with buffer D containing 0.5M NaCl and then with buffer D alone. The column was first developed with buffer D supplemented with 1 mM GTP, resulting in the specific elution of two poly peptides of ~17 and 20 kDa (see Fig. 2). Subsequently, the column was developed with buffer D containing 3 mM ATP, resulting in the specific elution of the 72- and 73-kDa stress proteins.

- [133] Welch 1985 differs from the claimed invention in using an ATP matrix to isolate heat-shock proteins in their native conformation [1014 at 1236 ("our purification scheme...resulted in the isolation of [heat-shock] proteins in what appears to be their native form"))] rather than an ADP matrix to isolate a heat-shock protein complexed with another protein.

- [134] A heat-shock protein bound to another protein is no longer in its native conformation.

- [135] Palleros (1994) teaches that ADP stabilizes the hsp-protein complexes unlike ATP, which triggers hsp-protein dissociation [e.g., 2030 at 13110]:

The effect of ADP and phosphate on complex dissociation triggered by Mg-ATP was studied by [size-exclusion chromatography/high performance liquid chromatography, SEC-HPLC] as a function of ADP and phosphate concentrations (Figs. 8 and 9). The complex between

DnaK and [reduced carboxymethylated α -lactalbumin, RCMLA] was formed by incubation at 37°C for 1 h, Mg-ADP or sodium phosphate were [sic] added at various concentrations, the mixtures were allowed to equilibrate for 10 min at room temperature, Mg-ATP (100 μ M) was added, and the mixtures were immediately analyzed by SEC-HPLC. In the absence of ADP, less than 10% of DnaK remained complexed with RCMLA after addition of Mg-ATP; as the concentration of ADP increases so does the fraction of complex: at [Mg-ADP] = 180 μ M, about 70% of DnaK remains in the complex, similar to the percent of complex detected after the same incubation period in the absence of nucleotides (Fig. 8, c and e).

- [136] One skilled in the art would, in view of Welch 1985 and Palleros 1994, have reasonably expected that hsp70-protein complexes could be recovered using the method of Welch modified by the use of an ADP matrix to stabilize the complex as suggested by Palleros.
- [137] Heat-shock proteins generally, and their protein complexes specifically, were the subject of significant research interest [2045 at 623-26].
- [138] Hsp-protein complexes were known to be involved in the presentation of antigens to the immune system [2045 at 624].
- [139] While UNM urges that such complexes are obvious once the particular heat-shock proteins are identified, it does not provide any particular motivation to isolate such complexes.
- [140] Note that earlier work by Srivastava, Udonon, and Blachere cited in UNM's involved patents [e.g., 2066 at 1:13-50] might provide motivation for making such complexes, but UNM has not cited that work against Fordham.

DISCUSSION

A. Substituting a new count

Fordham preliminary motion 1 seeks the substitution of a new count 4 for existing count 2. This motion is not opposed.

According to Fordham, it needs to broaden the count to eliminate any implicit ordering of the synthesis steps. Ordinarily, no order will be imputed to the steps of a claim unless the ordering is explicit in the claim or is functionally required. Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1342, 59 USPQ2d 1401, 1416 (Fed. Cir. 2001). Moreover, in proceedings in the Office, claims are ordinarily given their broadest construction reasonable in view of the underlying specification. In re Sneed, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983). Nevertheless, when the steps of a method build on other steps, such as by adding another reagent to a mixture formed in another step, there is necessarily an order to the steps. Arguably, such is the case here.

According to Fordham's uncontested assertion, the proposed count--though broader--defines the same invention as existing count 2. We accept this admission as providing an obvious relationship between the subject matter of existing count 2 and the proposed count. The purpose of the count is to define the scope of admissible proofs of priority (or derivation). Case v. CPC Int'l, Inc., 730 F.2d 745, 749, 221 USPQ 196, 199 (Fed. Cir. 1984). Consequently, it is possible to need a broader count to admit proofs to what is effectively the same invention. Compare Eaton v. Evans, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000) (proofs must provide all elements

of the count) with Aelony v. Arni, 547 F.2d 566, 570, 192 USPQ 486, 490 (CCPA 1977) (for the purposes of having an interference-in-fact, the inventions need only be patentably indistinct).

Broadening a count requires a proffer of the "best proof" outside the count to assess the reasonableness of the scope of the proposed count. Louis v. Okada, 59 USPQ2d 1073, 1076 (BPAI 2001). Fordham's proffer is an embodiment that differs from the count solely in the order of the steps.

Fordham preliminary motion 4 is GRANTED to the extent that the Fordham claim 65 portion of count 2 will be altered as proposed to eliminate any implicit ordering of the synthesis steps. The UNM portion of the proposed count will not be changed because the only suggestion in the motion that such relief is being sought appears to have been an error and in any case is not supported by the rest of the motion.

UNM moved in its preliminary motion 5 for the benefit of its 239 application as a constructive reduction to practice within the scope of count 4. The motion is not opposed. Since UNM had the benefit of its 239 application for count 2 and since the portion of the count based on UNM's 332 claim 22 is unchanged, the motion is GRANTED.

B. Fordham's entitlement to the benefit of its 391 application

Fordham has been accorded the benefit of its 391 application for counts 1-3. UNM preliminary motion 3 challenges this decision. Fordham preliminary motion 2 seeks benefit of the 391 application for count 4. UNM opposes.

Full scope support is not required to anticipate the subject matter of the counts

UNM's theory stems from the belief that Fordham must have support within the meaning of 35 U.S.C. 112[1] for the entire scope of the counts. This theory is based on a misapprehension of the holdings in Martin v. Johnson, 454 F.2d 746, 172 USPQ 391 (CCPA 1972); Weil v. Fritz, 572 F.2d 856, 196 USPQ 600 (CCPA 1978); and Hyatt v. Boone, 146 F.3d 1348, 47 USPQ2d 1128 (Fed. Cir. 1998).²³ In each of these decisions, references to "112 notwithstanding, the holding properly focused on the existence of support within the scope of the count.

It is long-established that an interference is about who loses on priority, not who is entitled to a claim. In re Kyrides, 159 F.2d 1019, 1022, 73 USPQ 61, 63 (CCPA 1947). A priority determination is a rejection for anticipation under 35 U.S.C. 102(g). E.g., Hyatt, 146 F.3d at 1350, 47 USPQ2d at 1129. Consequently, a constructive reduction to practice need only show a single embodiment that anticipates the subject matter of the count. Anderson v. Norman, 185 USPQ 371, 372 (Comm'r Pat. 1968) (a single embodiment is good enough for interference benefit, but not for patentability benefit);²⁴ accord Hunt v. Treppschuh, 523 F.2d 1386, 1389, 187 USPQ 426, 429 (CCPA 1975)²⁵ (original emphasis):

²³ Just recently, the author of the Hyatt decision cautioned against reading into cases holdings beyond what was actually decided. Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 873 n.10, 66 USPQ2d 1865, 1878 n.10 (Fed. Cir. 2003) (Newman, J., dissenting-in-part).

²⁴ The Federal Circuit has added a co-pendency requirement at least in the context of a rejection under 35 U.S.C. 102(e). In re Costello, 717 F.2d 1346, 1350, 219 USPQ 389, 391 (Fed. Cir. 1983). No challenge to co-pendency has been raised in this case.

²⁵ Cited with approval in Squires v. Corbett, 560 F.2d 424, 431, 194 USPQ 513, 517 (CCPA 1977). Squires elected to follow the reasoning of Hunt, rather than the apparently conflicting Den Beste v. Martin, 252 F.2d 302, 116 USPQ 584 (1958), which tellingly Squires dismisses, in part, as a product "of semantic

Another distinction is that Hunt's parent application is relied upon as a prior constructive reduction to practice; whereas in Smith v. Horne [450 F.2d 1401, 171 USPQ 755 (1971)] the disclosure was relied upon for a right to make the count. In the latter situation the requirements of the first paragraph of 35 U.S.C. 112 must be satisfied for the *full scope* of the count. In the former, however, the "112, first paragraph requirements need only be met for an *embodiment* within the count. The difference lies in the fact that a count is a vehicle for contesting priority and may not necessarily be allowable to a winning party or be proper under "112 (e.g. a phantom count).

This practice under "102(g) is consistent with the requirement of any anticipating reference or event: that it show possession of an enabled embodiment meeting all limitations. E.g., Transclean Corp. v. Bridgewood Svs., 290 F.3d 1364, 1370, 62 USPQ2d 1865, 1869 (Fed. Cir. 2002). In an interference the difference is that it is the subject matter of a count, not a claim, that is being anticipated by the constructive reduction to practice. In short, Fordham is entitled to the benefit of a constructive reduction to practice for a count if it "anticipates" the count, thus rendering UNM's claims corresponding to the count unpatentable under 35 U.S.C. 102(g), possibly in conjunction with 35 U.S.C. 103.

By contrast, compliance with "112[1] and 120 looks to whether Fordham is entitled to its claims—an important, but distinct, question. Perhaps the clearest example of UNM's misapprehension is the use of the "phantom count", 37 C.F.R. "1.601(f), which if it were a claim would typically not be patentable to at least one party because the party could not support its full scope. Squires, 560 F.2d at 433, 194 USPQ at 519;

confusion", 560 F.2d at 434, 194 USPQ at 519. Den Beste was overruled precisely because it extended the single-embodiment practice of constructive reduction to practice to right-to-make practice, which Squires concluded was governed by 35 U.S.C. 112[1], 560 F.2d at 435, 194 USPQ at 520, citing Hunt.

see also Case v. CPC Int'l, Inc., 730 F.2d 745, 749, 221 USPQ 196, 199 (Fed. Cir. 1984) (chastising Case for attacking the patentability of a phantom count under 35 U.S.C. 112).

If all of this is so well established, why is there persistent use of ¶ 112[1] and 120 in discussing constructive reductions to practice? No doubt it is "semantic confusion" of the requirements for claims (¶ 112[1] and 120) with the requirements of a rejection under ¶ 102(g) that Squires lamented. The confusion is understandable because both analyses focus on support for all limitations and enablement, and both require continuity. Nevertheless, it would be improper to import a full-scope requirement from ¶ 112[1] into a ¶ 102 analysis both as a matter of logic and in light of the case law. It has never been the law that an anticipation under ¶ 102 must be for the full scope of the subject matter of a count or of a claim.

While both Martin and Hyatt refer to ¶ 112[1] and 120 as part of their analyses, neither requires the constructive reduction to practice to support the full scope of the count. In Martin, scope is not an issue because the subject matter of the count is a species that is precisely described (albeit without a structural formula), 454 F.2d at 751, 172 USPQ at 395. In Hyatt, the court affirmed that Hyatt had failed to support a limitation in the count. 146 F.3d at 1354, 47 USPQ2d at 1131. Hence, Hyatt's downfall was not a lack of support for the full scope of the count, but rather a lack of support for any embodiment within the count because a limitation in the count was not disclosed. While the use of semantically confusing references to ¶ 112[1] and 120 in these Martin and Hyatt is regrettable, it does not infect the holding of the cases and cannot

compel us to overlook the dearer statement of the law (and actual holdings) in Hunt and Squires.

The Weil decision is more difficult to reconcile with the rest of the case law. At the outset, it is worth noting that the Weil court thought it was being consistent with Squires and Hunt. 572 F.2d at 866-67, 196 USPQ at 609. While it is true that Weil limits Hunt to the "special situation" where the count is drawn to a genus,²⁶ 572 F.2d at 865-66 n.16, 196 USPQ at 608 n.16, that situation is neither special nor surprising. If the count is a species, the support must be for the full scope of the count because nothing less would satisfy the requirement that all limitations of the count be met in the constructive reduction to practice. Consequently, the full-scope question can only arise for count involving a genus (or a range or an analogously broad and inclusive definition of an invention).

The difficulty arises in Weil's holding that a best-mode determination is "ancillary to priority" because it is part of a $\text{---} 112[1]/\text{---} 120$ analysis for determining whether Fritz was entitled to be the senior party. Implicitly, Weil grounds its holding on the premise that compliance with $\text{---} 120$ is required for benefit of an earlier constructive reduction to practice. On its face, the reasoning underlying the Weil holding is at odds with Squires and Hunt, the decision's insistence to the contrary notwithstanding.²⁷ We need not

²⁶ The count in Weil was a method of using a chemical species.

²⁷ Weil never explains why it is consistent with Squires and, on its face, appears to perpetuate the "semantic confusion" Squires tried to set straight. The closest Weil comes to an explanation is in footnote 17, in which it notes case law saying that a constructive reduction to practice must be "a complete and allowable application". This analysis suggests that the Weil court might have seen a failure to comply with $\text{---} 112[1]$ for the subject matter of the count to constitute an abandonment, suppression, or concealment of the invention within the meaning of $\text{---} 102(g)$. Neither Weil nor any other precedent has articulated such a theory, however. Thus, Weil leaves us with an apparent best-mode requirement for an anticipation under $\text{---} 102(g)$ that cannot

resolve the difficulty in this case because the holding in Weil addresses a best-mode requirement,²⁸ not a full-scope requirement. Consequently, the holding in Weil does not compel a full-scope description or enablement requirement in the present case.

The counts are the phantom counts

A second problem with UNM's analysis arises from the fact that each of the counts is a phantom count composed of two or more claims of the parties; in the case of the first two counts, one claim from each party.²⁹ As previously explained, neither party is expected to have support for the full-scope of a phantom count. If we accepted UNM's argument that the hsp70 family does not really form a genus, then we would still have interfering subject matter in the first two counts between Fordham's hsp70 subject matter and UNM's Markush-format subject matter that includes hsp70 as an alternative.³⁰ Hence, even accepting UNM's premise, Fordham need only support an hsp70 embodiment for the first two counts in order to be entitled to the benefit of its earliest constructive reduction to practice. In this sense, counts 1 and 2 would actually be species counts because the non-hsp70 alternatives should be ignored. Thus,

otherwise be reconciled with precedent or practice.

²⁸ A best mode, by its very nature, is not a full-scope inquiry because the existence of a best mode presupposes the existence of other modes that are not also best modes.

²⁹ This particular variant of the phantom count has come to be known as a "McKelvey count" after the first administrative patent judge to be widely associated with its use. While any count formulation methodology involves choices and trade-offs, one clear advantage of the McKelvey count is that it usually simplifies the benefit analysis because a party need usually only show support for an embodiment within the scope of one of its own claims.

³⁰ If we were to accept that the hsp70 family is not a proper genus, then the first two counts should be further amended to exclude the non-hsp70 alternatives since they do not interfere and so proofs of priority directed to non-hsp70 alternatives should not be admitted. We note that neither party has requested such a narrowing of the counts.

whether we adopted UNM's view of counts 1 and 2 or not, the outcome would be the same.

Count 3 is also a phantom count, but it is based entirely on UNM claims and does not include hsp70 as an alternative. Count 3 only makes sense as a count if one assumes that many hsp70 family members (at least DnaK; one of Ssa, Ssb, or Ssc; and one of Grp75 or Grp78(Bip)) are patentably indistinct. Once again, it is instructive that neither party has moved to change the count on the basis that this assumption is incorrect.

We found above that Fordham provided blaze marks sufficient for one skilled in the art to believe that Fordham possessed a DnaK embodiment within the scope of count 3, albeit one that rested on its similarity to the explicitly taught hsp70 embodiment. Hence, the real question becomes whether Fordham also enabled the DnaK embodiment.

As the movant to deny benefit, UNM has the burden of proof. 37 C.F.R. 1.637(a). In any case, a reference used for anticipation, in this case Fordham's earliest constructive reduction to practice, should be presumed to be enabling absent a showing to the contrary. Cf. Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 nn.21 and 22 & text, 65 USPQ2d 1385, 1416 nn.21 and 22 & text (Fed. Cir. 2003) (dicta in part) (providing policy reasons for placing the burden regarding the enablement of a reference on the party attacking the reference); accord In re Epstein, 32 F.3d 1559, 1568-69, 31 USPQ2d 1817, 1823-24 (Fed. Cir. 1994) (enablement of reference is presumed). Even to the extent that UNM's challenge can be understood to

be a patentability attack under \S 112[1], a presumption of enablement attaches to Fordham's disclosure. In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995); In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). In any case, UNM has not provided a basis for believing that one skilled in the art would have doubted Fordham's ability to produce a purified ADP-DnaK-peptide complex based on its disclosure of a method for producing ADP-hsp70-peptide complexes. Indeed, the testimony of UNM's expert, Dr. Welch, supports the inference that one skilled in the art would have expected members of the hsp70 family to have similar binding affinities for adenosine nucleotides.

Other hsp families

UNM's concern about Fordham's putative lack of support for non-hsp70 family heat-shock proteins is particularly wide of the mark because the counts, even construed to the outer limits of reasonableness, are limited to hsp70 family embodiments. While broader claims that are not limited to hsp70 family heat-shock proteins are designated as corresponding to the count, this designation simply reflects the fact that the broader claims would be anticipated by priority proofs to the narrower subject matter of the counts. It is long and well established that loss of narrower subject matter in an interference bars a losing party from claiming broader subject matter encompassing the lost count absent (absent a sufficient antedating effort for the generic subject matter). E.g., In re Zletz, 893 F.2d 319, 322-23, 13 USPQ2d 1320, 1322-23 (Fed. Cir. 1989); In re Kyrides, 159 F.2d 1019, 1022, 73 USPQ 61, 63 (CCPA 1947).

Incorporation of essential matter into Fordham's specification

Although we found above that Fordham has support for an embodiment within the scope of the counts without recourse to any of the incorporated materials, we note that incorporation-by-reference is rarely a proper basis for finding a lack of description in a reference. See Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282, 54 USPQ2d 1673, 1679 (Fed. Cir. 2000) (relying on incorporated material for anticipation). Even under a $\text{MPEP } \S 112[1]$ analysis, as long as the subject matter to be incorporated is identified with reasonable precision and explicitly incorporated, the proper remedy in an application is to require the actual incorporation of the material prior to issuing a patent based on the application. MPEP $\text{ } \S 608.01(p)$, I.A. An incorporation-by-reference of essential material in a benefit application is not considered to be the basis for a rejection even under a $\text{MPEP } \S 120$ analysis. Ex parte Maziere, 27 USPQ2d 1705, 1706-07 (BPAI 1993).

It is certainly possible to imagine abuses, for instance, incorporation-by-reference of an entire textbook or laboratory manual, that can then be selectively interpolated as the need arises. The requirement for particularity in identifying the incorporated material addresses this abuse, which in any case is a function of the size of the incorporation, such that a short article will require less particularity in identifying the incorporated material than a large tome. We do not rely on the incorporated material for finding Fordham to have support for each count, but we note that Fordham's reference to specifically identified journal articles is not on its face an abuse of incorporation-by-reference practice.

UNM preliminary motion 3 is DENIED.

Fordham's benefit for count 4

Count 4 is a broader version of count 2. Since Fordham had benefit for the narrower count, it follows that Fordham is entitled to benefit for the broader count unless UNM provides a good basis for denying the motion in its opposition. UNM opposition 2, however, has the same defects as its preliminary motion 3. Consequently, Fordham preliminary motion 2 is GRANTED.

C. Designating additional Fordham claims as corresponding to counts

UNM preliminary motion 4 seeks to have Fordham claims 94 and 95 designated as corresponding to count 3. This motion is not opposed.

Correspondence is an accounting mechanism for determining what claims would be lost to the party that loses the count. As such correspondence is a provisional rejection of designated claims as anticipated by or obvious in view of a claim indisputably corresponding to the count. Cf. In re Deckler, 977 F.2d 1449, 1452, 24 USPQ2d 1448, 1450 (Fed. Cir. 1992) (the losing party in an interference is not entitled to a patent covering claims patentably indistinguishable from the lost count); 37 C.F.R. 1.637(c)(3). In failing to oppose UNM's preliminary motion 4, we understand Fordham to be conceding the unpatentability of its claims 94 and 95 should it lose the priority contest for count 3. 37 C.F.R. 1.658(c). Consequently, UNM preliminary 4 is GRANTED.

Fordham preliminary motion 3 seeks to add claim 96 and have it designated as corresponding to count 2. The motion is not opposed.

We have already granted Fordham's request to substitute count 4 for count 2. Consequently, there is no longer a count 2 to which claim 96 could correspond. When asked about this at the hearing, Fordham's counsel indicated that substitution of count 4 would moot the need for claim 96.

Proposed claim 96 is the same as the modified version of claim 65 that is now part of count 4. Fordham's motion indicates that adding the claim is necessary to allow it to present its best proofs. The admissible proofs, however, are governed by the count, not the corresponding claims. Consequently, the substitution of count 4 for count 2 has already provided Fordham with the relief it seeks, while the addition of claim 96 is unnecessary and would be unhelpful to Fordham in any case.

Consequently, Fordham preliminary motion 3 is DENIED.

D. Correspondence of UNM claims

Designation of some claims as not corresponding

UNM preliminary motion 1 seeks to have UNM 332 claims 8, 9, and 11 designated as not corresponding to count 1 and UNM 332 claims 20, 21, and 23 designated as not corresponding to count 2. As movant, UNM has the burden of proof. 37 C.F.R. § 1.637(a).

For the purposes of deciding this motion, we will construe references to count 2 to mean count 4, which continues to be based in part on UNM 332 claim 22. Again, the test is whether a claim to be undesignated would be barred if UNM were to lose on priority. Deckler, 977 F.2d at 1452, 24 USPQ2d at 1450. No one appears to maintain that the added limitations in claims 8, 9, 11, 20, 21, and 23 are anticipated, so

the question of patentable distinctness will depend on whether the subject matter of the claims would have been obvious in view of undisputed interfering subject matter.

The premise for UNM's argument is that while the count is directed to a method for purifying or synthesizing hsp70 family proteins, the claims to be undesignated are directed to methods for purifying or synthesizing other non-hsp70 family heat-shock protein complexes. UNM correctly points out that the claims have different primary (sequence), quaternary (multi-protein complex), and crystal structures. Moreover, they are found in different organisms and in different organelles of such organisms, suggesting differences in function. Finally, they have different substrates and are induced by different levels of stress.

Fordham's argument, however, is more to the point. For the claimed methods to work, the heat-shock protein in question must have an affinity for ADP while the heat-shock protein is bound to another protein. While it would be possible to imagine reasons why the structure of a given heat-shock protein might cause a failure of the method,³¹ a person having ordinary skill in the art would expect that a heat-shock protein with an affinity for ADP and proteins would be a likely candidate for purification by the same method. The structural similarities in the relevant binding domains of the heat-shock proteins would have given rise to a reasonable expectation that the method would work as intended. Cf. In re Merck & Co., 800 F.2d 1091, 1096, 231 USPQ 375,

³¹ For instance, one of the post-critical date articles discussed above suggested that the ATP-binding site of hsp110 is normally hidden, although there was also post-critical date evidence to the contrary. If the structure of hsp110 blocks its ATP-binding site, then ATP/ADP-binding would be unlikely.

379 (Fed. Cir. 1986) (structural similarities between antidepressant and another compound support a reasonable expectation of similar properties).

The filing date is the relevant time for gauging obviousness. Epstein, 32 F.3d at 1564 n.4, 31 USPQ2d at 1820 n.4. At that time, the evidence suggested that hsp60 family members share this affinity with hsp70 family members. Gp96 also shares an affinity for ADP and proteins, although its interaction with ATP appeared to differ from that of hsp70. In particular, ATP does not appear to cause dissociation of the gp96-protein complex, so there would be less of an incentive to move from a ATP matrix to an ADP matrix for the purpose of isolating gp96 complexes.³² The hsp110 family presents a harder question because it was much more weakly characterized than other heat-shock proteins and the post-critical date evidence continues to be equivocal. Nevertheless, at the time of UNM's invention, the state of the art pointed to both protein-binding and ATP-binding for hsp110.

The key question is what would a person having ordinary skill in the art have considered to be an obvious application of the method to a heat-shock protein as of UNM's earliest effective filing date? The articles at the time show a good deal of unpredictability in the specific characteristics of each heat-shock protein, particularly its choice of substrates. Nevertheless, protein-binding and ATP-binding were among the first things studied and had been at least tentatively identified for at least one Markush choice in each of the claims to be undesignated. It is instructive to note in this context

³² Note that an alternative way of isolating gp96 would not have to be better to be obvious. One motivation to use an ADP matrix rather than an ATP matrix could be that the ADP matrix is on hand, while the ATP matrix is not.

that UNM was sufficiently confident in the understanding of persons having ordinary skill in the art to provide essentially no enabling details for heat-shock proteins other than hsp70. Cf. Epstein, 32 F.3d at 1568-69, 31 USPQ2d at 1823-24, in which the applicant's specification provided no more guidance than the references. UNM apparently viewed the listed heat-shock proteins as an interchangeable class for the purposes of the claimed method. The state of the art at the time was consistent with UNM's view. We see no reason to diverge from that view now. The question is a close one, particularly given the post-filing evidence showing the continuing unsettled state of the art, but a preponderance of the evidence suggests that a person having ordinary skill in the art at the time UNM filed its applications would have considered isolation of hsp-protein complexes using an ADP matrix to have been obvious for any heat-shock protein with an ATP-binding domain and a protein-binding domain in view of Fordham's claimed hsp70 invention.

UNM has not carried its burden of showing that UNM 332 claims 8, 9, and 11 do not correspond to count 1 and UNM 332 claims 20, 21, and 23 do not correspond to count 4. Consequently, UNM preliminary motion 1 is DENIED.

Designation of some additional claims as corresponding

Fordham preliminary motion 4 seeks to have UNM 332 claims 2 and 6 designated as corresponding to count 1, UNM 332 claims 14 and 18 designated as corresponding to count 2,³³ and UNM 716 claims 7-12 designated as corresponding to count 3. As movant, Fordham has the burden of proof. 37 C.F.R. § 1.637(a).

³³ Now count 4, which still includes UNM 332 claim 13 as an alternative.

We start by dispatching an argument UNM raises in opposition, that "same patentable invention" in 37 C.F.R. § 1.637(c)(3) means "anticipation". The phrase "same patentable invention" is defined to include an obviousness analysis expressly. 37 C.F.R. § 1.610(n). Cf. Aelony v. Arni, 547 F.2d 566, 570, 192 USPQ 486, 489-90 (CCPA 1977) (claims interfere when they are obvious in view of each other). We do not understand any of Fordham's arguments to rely on anticipation and so will evaluate them in terms of obviousness.

UNM 332 claims 2, 6, 14, and 18

For claims 2, 6, 14, and 18, all of which require a GTP (or other non-adenosine nucleotide) elution step to eliminate contaminants, Fordham's case of obviousness stumbles, however, because it fails to show any evidence regarding the relative affinities of contaminants and heat-shock proteins for GTP versus ADP. It is almost certainly true that some (though not necessarily all) contaminating proteins would have a higher affinity for GTP. Were this enough, then Fordham might have carried its burden. The problem, however, arises with the relative affinity of the targeted heat-shock protein for ADP versus GTP. While Welch 1985 establishes that at least some heat-shock proteins would rather bind to ATP than GTP, we have been pointed to no evidence of a similarly stronger affinity for ADP. The fact that heat-shock proteins can and do bind to ADP does not establish that they bind to it particularly strongly, particularly when competing with another common cellular purine nucleotide. At best, this is an invitation to experiment rather than a showing of obviousness. In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988).

UNM 716 claims 7-12

As noted in the fact-finding, we do not consider the hsp110 family proteins of UNM 716 claim 7 to be anticipated by the hsp70 family proteins enumerated in UNM claims 13, 19, and 25. Moreover, claims 7-12 are composition claims and are not stated in terms of a product-by-process. Consequently, Fordham's obviousness analysis must proceed from the obviousness of hsp110 family members from the enumerated hsp70 family members.

While the parties dispute whether the hsp110 family is part of the hsp70 family based on the degree of sequence and domain identity or similarity between hsp110 and DnaK, we are provided very little motivation for the substitution of an enumerated (in claims 13, 19, and 25) hsp70 family member with an hsp110 subfamily member, or with the modification of such an hsp70 family member into an hsp110 family member. In the context of UNM's disclosure, the only thing linking these heat-shock proteins is the fact that they (and members of other hsp families) may be purified in the same way. Since claim 7 is not a product-by-process claim, however, this process similarity does not help make out a case for obviousness. We cannot conclude that hsp110 complexes would have been obvious in view of other hsp70 complexes. If anything, the evidence suggests that a person having ordinary skill in the art would have expected hsp110 complexes to have been very different.

Fordham has not carried its burden of showing that UNM 332 claims 2 and 6 correspond to count 1, UNM 332 claims 14 and 18 correspond to count 4, or that UNM

716 claims 7-12 correspond to count 3. Consequently, Fordham preliminary motion 4 is DENIED.

E. Patentability of Fordham claims 60, 62-75, 78-80, 82-90, and 92-95

UNM preliminary motion 2 seeks to have Fordham claims 60, 62-75, 78-80, 82-90, and 92-95 held unpatentable under 35 U.S.C. 103. As movant, UNM has the burden of proof. 37 C.F.R. § 1.637(a).

"A showing of obviousness requires a motivation or suggestion to combine or modify prior art references, coupled with a reasonable expectation of success[.]" Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.2d 1339, 1354, 65 USPQ2d 1961, 1971 (Fed. Cir. 2003). In this case, both the motivation and the expectation of success are obstacles to granting UNM's motion.

The prior art UNM cited suggests that an ADP substrate could be substituted for the ATP substrate in the method of Welch 1985 if one seeks to isolate hsp-protein complexes. The motivation for the modification, however, hinges on the desirability of making hsp-protein complexes. "The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Without a motivation to make such complexes, the fact that it could be done is academic. What motivation there is appears to come from the work of one of Fordham's inventors and was not cited by UNM against Fordham.

Moreover, it is not clear why a person having ordinary skill in the art would expect the substitution to work. After all, Welch 1985 emphasized that its method isolated

heat-shock proteins in their native form. Palleros, using a different method, found that adding ADP to (or substituting it for ATP in) the mobile phase of the chromatography system had the effect of stabilizing the complex much more than ATP alone. Assuming that a person having ordinary skill in the art had motivation to isolate hsp-protein complexes, the combined teachings of Welch 1985 and Palleros provide an experiment to try rather than a reasonable expectation of success. See In re Dow Chemical Co., 837 F.2d, 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985) (rejecting an "obvious to experiment" approach).

UNM is deemed to have conceded the unpatentability of its own claims over the prior art except to the extent UNM specifically argues otherwise. 37 C.F.R. § 1.637(a). UNM has only argued for the patentability of UNM 332 claims 8, 9, 11, 20, 21, and 23. While UNM did not prove sufficient motivation to justify a conclusion of obviousness with respect to Fordham's claims, UNM's disclosure could be taken as an admission of motivation in the prior art. Because UNM has not had a chance to address what would be, in effect, a new ground of rejection, we will not pursue it here.

UNM has not carried its burden of showing with a preponderance of evidence that Fordham's claims are not patentable. Consequently, UNM preliminary motion 2 is DENIED.

Fordham has moved to strike UNM exhibits and reply relating to UNM preliminary motion 2. In light of the disposition of that motion, Fordham miscellaneous motion 2 is DISMISSED as moot.

Fordham has also moved to defer any effort to antedate the references. Again, in light of the disposition of UNM preliminary motion 2, Fordham miscellaneous motion 3 is DISMISSED as moot.

ORDER

Upon consideration of the preliminary motions and the cited evidence, it is:

ORDERED that UNM preliminary motions 1, 2, and 3 be DENIED;

FURTHER ORDERED that UNM preliminary motions 4 and 5 be GRANTED;

FURTHER ORDERED that Fordham preliminary motion 1 be GRANTED as discussed above;

FURTHER ORDERED that Fordham preliminary motion 2 be GRANTED;

FURTHER ORDERED that Fordham preliminary motions 3 and 4 be DENIED;

FURTHER ORDERED that Fordham miscellaneous motions 2 and 3 be DISMISSED as moot;

FURTHER ORDERED that this interference be remanded to the administrative patent judge designated to handle the interference; and

FURTHER ORDERED that a copy of this decision be given a paper number and be entered in the administrative records of UNM's 5,747,332 patent and Fordham's 09/090,754 application.

RICHARD E. SCHAFER
Administrative Patent Judge

RICHARD TORCZON
Administrative Patent Judge

CAROL A. SPIEGEL

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Interference No. 104,761
Univ. of New Mexico v. Fordham Univ.

Paper 98
Page 49

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